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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,085	03/04/2002	George N. Lambrou	OP/4-31902A/USN	4270

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EXAMINER	
KWON, BRIAN YONG S	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 09/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/090,085	LAMBROU ET AL.	
	Examiner	Art Unit	
	Brian S Kwon	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) *3,4,7,8,11 and 12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5,6,9 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicants Response to Restriction Requirement Acknowledged

1. Applicants election with traverse the Group I, claims 1-2, 5-6 and 9-10, is acknowledged.

Applicants traverse the restriction requirement on the grounds that there is a relationship and connection between the Claims of Group I and Groups II and III. Applicants argue that since the method set forth in the Group II or Group III invention requires a subgenus of a compound that is recited in the method of Group I invention, the Claims of Group I are related and connected to the Claims of Group II and III.

Applicants are correct that the subgenus of a compound that is recited in the method of Group I invention is required in Group II and III invention. However, Group I invention is unrelated from II or III by different modes of operation or different functions (MPEP § 806.04, MPEP § 808.01). For example, Group II invention, drawn to a method of maintaining or inducing hyperpolarization in the cell membranes of a mammal, can be practiced with the different modes of operation (i.e., opening of chloride channel, glutamate-gated chloride channel, and etc...). Furthermore, Group III invention, drawn to a method for treating conditions and disease states characterized by excessive cell membrane depolarization, can be practiced with different modes of operation or different functions (i.e., loop diuretics, calcium channel blocker, beta-blocker, etc...). Therefore, the claimed invention would be "independent" and "distinctive", each from the other.

Furthermore, with respect to applicants argument "there would be no burden in searching the entire groups", the search of the entire groups in the non-patent literature (a significant part of a thorough examination) would be burdensome. Therefore, the requirement is still deemed

of a thorough examination) would be burdensome. Therefore, the requirement is still deemed proper, and made Final. Claims 3-4, 7-8 and 11-12 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected claims, the requirement having been traversed in Paper No. 5.

2. Claims 1-2, 5-6 and 9-10 are currently pending for the prosecution on the merits.

Priority

3. Applicant's claim for benefit of 60/275,316 filed on 03/13/2001 (domestic priority) under 35 U.S.C. 119(e) is acknowledged.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-2, 5-6 and 9-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Reed (WO 98/41208).

The claims read on a method for opening potassium channels in the cell membranes of a mammal in need of such treatment comprising administering to the mammal an effective amount of a compound of the formula (in claim 1 and claim 2), namely unoprostone isopropyl, wherein said condition or disease state is hypertension, pulmonary hypertension, asthma, interstitital cystitis, urinary incontinence and other urogenital disorders, ischemic bowel disease,

gastrointestinal motility disorders, arrhythmias, peripheral vascular disease, congestive heart failure, dysmenorrhea, angina or alopecia.

Reed teaches the ophthalmic administration of isopropyl unoprostone for the treatment of ocular hypertension, wherein said isopropyl unoprostone is administered within the dosage range of about 0.001 to about 0.30 weight percent (Examples 1-3). Examples 1-3, especially Table I, shows the efficacy of about 0.12% to about 0.18% isopropyl unoprostone in lowering intraocular pressure wherein about 30 microliters of the formulation were instilled into the eye of a rabbit.

Although Reed is silent about the activity of isopropyl unoprostone in opening potassium channels in the cell membranes of a mammal, such property or characteristics deems to be inherent to the prior art method of treating ocular hypertension. Especially in light of the instant disclosure (page 9, lines 7-12), the prior art administered dosage of isopropyl unoprostone in treating ocular hypertension lies well within the instantly claimed dosage range. Therefore, the prior art method directing the administration of isopropyl unoprostone inherently possessing a therapeutic effect for the same ultimate purpose as disclosed by Applicants anticipates Applicants's claims even absent explicit recitations of the mechanism of action.

Conclusion

5. No Claim is allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (703) 308-5377. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Brian Kwon

ZOHREH FAY
PRIMARY EXAMINER
GROUP 1600